September 17, 2004

SUPPORTING STATEMENT FOR
AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection:

Data Acquisition for Anticipated Residue and Percent of Crop Treated
OMB No.: 2070-0164; **EPA No.:** 1911.02

1(b) Short Characterization/Abstract

This information collection request (ICR) involves an information collection activity related to the statutorily mandated re-evaluation of previous Agency decisions regarding the establishment of a tolerance (maximum residue limit) for pesticide residues on food or feed crops.

The use of pesticides to increase crop production often results in pesticide residues in or on the crop. To protect the public health from unsafe pesticide residues, the Environmental Protection Agency (EPA) sets limits on the nature and level of residues permitted pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). A pesticide may not be used on food or feed crops unless the Agency has established a tolerance for the pesticide residues on that crop, or established an exemption from the requirement to have a tolerance.

It is EPA's responsibility to ensure that the maximum residue levels likely to be found in or on food/feed are safe for human consumption through a careful review and evaluation of residue chemistry and toxicology data. In addition it must ensure that adequate enforcement of the tolerance can be achieved through the testing of submitted analytical methods. Once the data are deemed adequate to support the findings, EPA will establish the tolerance or grant an exemption from the requirement of a tolerance.

This ICR will enable EPA's Office of Pesticide Programs (OPP) to obtain information needed to re-evaluate the Agency's original tolerance decisions as mandated by the Food Quality Protection Act of 1996 (FQPA), which amended the two primary statutes regulating pesticides, i.e., FFDCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Among other things, FQPA amended FFDCA to authorize the Agency to use anticipated or actual residue (ARs) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide residue. However, the law also requires that tolerance decisions based on ARs or PCT data be verified to ensure that residues in or on food are not above the residue levels relied on for establishing the tolerance.

In order to conduct the required re-evaluation, a Pesticide Registrant may be required to submit specific data necessary to demonstrate that residues do not exceed the residue levels used to establish the tolerance.

The burden and costs associated with establishing a tolerance or an exemption from a tolerance are covered under ICR number 2070-0024, *Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients.* This ICR only addresses the burden and costs

associated with the information collection activities related to the re-evaluation of tolerances pursuant to FFDCA section 408(b)(2) (Attachment A).

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

FIFRA sections 3(a) and 12(a)(1) require a person to register a pesticide product with the EPA before that product may be lawfully sold or distributed in the United States. A pesticide registration is a license that allows a pesticide product to be sold and distributed for specific uses under specified terms and conditions such as use instructions and precautions. A pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5). Under FFDCA section 408, before a pesticide may be used on food or feed crops, the Agency must establish a tolerance for the pesticide residues on that crop or established an exemption from the requirement to have a tolerance.

The authority for the information collection activities contained in this ICR can be found in FFDCA Section 408(b)(2)(E) and (F), which authorizes the Agency to use anticipated or actual residue (ARs) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide. The FFDCA requires that if AR data are used, data must be reviewed five years after a tolerance is initially established. If PCT data are used, the FFDCA affords EPA the discretion to obtain additional data if any or all of several conditions, including but not limited to the following, are met:

- the existing data have been found unreliable;
- exposure estimates underestimate exposures for any significant population group;
- dietary exposure must be re-evaluated periodically

As noted above, when re-evaluating tolerance actions, Section 408(f) of FFDCA generally requires EPA to issue DCIs whenever ARs data have been relied on, and affords the EPA the discretion to issue DCIs when PCT data have been relied on. OPP issues a DCI to affected registrants under the authority of FIFRA section 3(c)(2)(B) (Attachment B). The data obtained from the DCIs are needed to reassess the risk and to confirm that use of a pesticide is not likely to cause unreasonable adverse effects to human health or the environment.

2(b) Practical Utility/Users of the Data

OPP will evaluate the data obtained from registrants to ensure that residues in or on food are not above the residue levels relied on for establishing the tolerance. If the submitted residue data demonstrates that the residue levels are above the levels relied on for establishing the tolerance, EPA will take appropriate action to modify or revoke the tolerance.

NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-duplication

OPP supports several activities to eliminate duplication and promote efficiency in information collection efforts for registration. Before any DCI is conducted, internal files are referenced to determine whether the required data is already on hand. Since much of the percent-crop-treated information can be obtained internally, DCIs will only be issued when more data is necessary. The data for anticipated residues, on the other hand, is unique to the requirements of FIFRA, and, therefore, must be submitted to the Agency.

OPP also publishes a list of data submitters and encourages the industry to act cooperatively in the development of data or in its use. OPP allows cost-sharing agreements among manufacturers of specific pesticide chemicals in order to minimize the duplication of laboratory tests conducted for this program. All DCI notices explain the statutory provisions for cost-sharing agreements under FIFRA.

3(b) Public Notice Required Prior to ICR Submission to OMB

In preparing to renew this ICR, EPA published a notice in the Federal Register which provided a 60-day public notice and comment period on the draft ICR(see FR 25079, May 5, 2004). The Agency did not receive any public comments.

3(c) Consultations

Before a particular DCI is issued under either program, the procedures for both programs provide several opportunities for consultations with the affected registrants, as well as with the public and other interested parties.

In the initial stage of AR/PCT reviews, the Agency announces its intent to conduct such a review and require additional studies. Registrants and other interested parties have the opportunity to comment on the Agency's intent. Generally the Agency consults with registrants before a data call-in notice is issued to discuss the Agency's need for particular information and the protocol to be used to conduct the study. OPP is always open to communications with registrants concerning any issue they may have with the requirements for data. As mentioned, registrants may request waivers of data requirements if they believe that OPP can properly evaluate their pesticide without additional data. The Agency may modify its DCI requirements if warranted by information provided by registrants or the public. In addition, registrants may respond to the DCI by requesting waivers of data requirements if they believe that OPP can properly evaluate their pesticide without additional data. The Agency has already on several occasions discussed the statutory requirements and data requirements for the AR/PCT reviews with the stakeholders.

For this renewal, EPA consulted with five organizations that might have a specific interest in this ICR. EPA staff contacted the representatives listed in Attachment J by telephone and e-mail and asked them for feedback on the burden and cost estimates in the ICR. The solicitation for consultation included three registrants and two industry trade associations, two registrants

replied. The Agency did not receive any comments to the proposed ICR during the first public comment period. While the Agency provided responses to the comments made in the consultation process (see Attachment K), no changes to the burden hours or cost were made to the ICR as a result of any of the comments received.

3(d) Effects of Less Frequent Collection

Information is collected one time within the five years preceding the reliance on ARs or PCT data. This one time collection is required by (FFDCA 408(b)(2)(E)(I) and 408(b)(2)(F) and cannot be collected less frequently.

3(e) General Guidelines

The only guideline established under the Paperwork Reduction Act (PRA) that is exceeded in this collection is the time period for retaining records. EPA requirements in 40 CFR 169.2(k) state that records containing research data relating to registered pesticides be retained as long as the registration is valid and the producer remains in business. Registrations are valid until they are canceled by the Agency, either by request of the registrant or on the initiative of EPA. Since most pesticides remain on the market for 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records not be required to be retained for more than three years is exceeded in this program.

The forms associated with this ICR are also used for other information collection activities that are approved under separate OMB Control numbers, e.g., 2070-0057, 2070-0060, 2070-0107 and 2070-0122. Specifically, Certification of Attempt to Enter into an Agreement with Registrants for Development of Data (EPA Form 8570-32) (Attachment E), Certification with Respect to Citation of Data (in Pesticide Registration (PR) Notice 98-5) (EPA Form 8570-34) (Attachment F), Data Matrix (also in PR Notice 98-5) (EPA Form 8570-35) (Attachment G), Data Call-In Response Form (EPA Form No. pending) (Attachment C), and the Requirements Status and Registrant's Response Form (EPA Form No. pending) (Attachment D).

When EPA submitted the previous ICR to OMB for review in 2000, the Agency requested permission, in accordance with 5 CFR 1320.5(a)(1)(iii)(C), to discontinue the display of expiration dates on these forms in the future because the forms had not changed after many years of use and were not expected to change in the future. OMB approved that ICR request, and EPA has therefore continued to omit the expiration dates on these forms.

The Data Call-In Response Form and the Requirements Status and Registrant's Response Form have been approved with DCI related ICRs by OMB for several years, although no official EPA Form number had been assigned in the past. These two forms are automatically generated by EPA's computer databases and are pre-populated with information that is specific to each individual registrant that receives a Data Call-In notice for a given pesticide. These forms will not be widely accessible to general public through EPA's Internet site. Instead, EPA will continue to generate the pre-populated, registrant-specific forms through the Agency's computer system when preparing to issue Data Call-In notices. EPA is currently assigning official form numbers for these forms to help clarify their OMB approval status. As discussed in the paragraph above, EPA will also continue to omit expiration dates for these forms.

Also, OMB's regulations require agencies to provide a statement indicating whether the proposed collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and an explanation of the decision (5 CFR 1320.5(a)(iii)(E)). In December 2001, EPA announced that registrants now have the option to electronically submit the underlying study data required by the Agency to ensure that a given pesticide will not pose unreasonable adverse effects to human health and the environment. At this time, OPP is not offering a fully electronic submission option. Additionally, OPP is not yet prepared to accept the electronic submission of any forms listed in this ICR. Forms-based submissions likely would be transmitted via the World Wide Web and neither OPP nor the Agency's Office of Environmental Information have developed the information technology approaches that would adequately protect FIFRA Confidential Business Information submitted in this way. Therefore, the public should note that the electronic submission option currently applies only to the submission of studies and supplemental files.

Ordinarily, registrants would be required to submit 3 paper copies of study data to EPA. Under this hybrid option, registrants need only submit 2 paper copies if they submit the required study data in Adobe Acrobat Portable Document Format (PDF) on a compact disc. Once EPA staff have become familiar with the electronic submission process and the technology, OPP believes that this option will allow the Agency to achieve operating efficiencies in the regulation of pesticides through the promotion and facilitation of the electronic submission process, including the delivery, review, data interchange capability and archiving of data supporting national pesticide registration. The time normally required for OPP to complete its review of the data should be shortened, thereby allowing faster regulatory decision-making. The Agency also believes that, once the registrant community has become familiar with the electronic submission process and the technology, registrants would be able to prepare their data submissions in less time. Registrant submissions of study data are often voluminous. Some submitted studies may be several thousand pages long. OPP expects that registrants will spend less time and money preparing copies and sending their submissions using the hybrid paper-electronic submission option, and stand to benefit from the efficiencies that EPA expects to experience during data reviews.

Finally, the terms of clearance outlined by OMB when this ICR was approved in 2001 required that EPA not issue any DCI unless it had first been approved by relevant high-level management in the Office of Pesticide Programs, as well as reviewed and approved by OMB. In the detailed DCI approval request, EPA was to estimate the respondent burden and costs related to specific DCIs before they were issued, including the total cost for performing the required study(s), and the associated paperwork related burden and costs. OMB would then review the information collection activities associated with each individual DCI to ensure that the collection of information was the least burdensome necessary for the proper performance of the agency's functions and that the collection of information was not duplicative of information otherwise accessible to the agency. If OMB raised no questions during the 15 work day review period, EPA could issue the DCIs. During the last 3 year approval period for this ICR, the Agency did not need to seek approval for any specific DCIs.

3(f) Confidentiality

Except as provided in FIFRA section 10(d)(1)(A), (B) or (C), health and safety data submitted by registrants under FIFRA must be made available by the Agency upon request from anyone not affiliated with a multi-national pesticide firm. These exceptions, however, specifically prohibit disclosure of the inert ingredients in a pesticide, or of it manufacturing, quality control processes, sales and production data, or trade secrets.

Registrants may claim at the time of submission that specific data are subject to treatment as confidential for reasons other than falling within the exclusions for mandatory release. All data subject to such claims, or falling within FIFRA section 10(d)(1)(A), (B), or (C) are handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Security Manual. The manual requires that all CBI must be marked or flagged as such, all CBI must be kept in secure (double-locked) areas, and all CBI intended to be destroyed must be cleared by a Document Control Officer and shredded.

3(g) Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity, and this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

The North American Industrial Classification System (NAICS) code for respondents to this ICR is **325320** (Pesticide and other Agricultural Chemical Manufacturing).

4(b) Information Requested

(i). Data items, including record keeping requirements

The kinds of data that may be the subject of a DCI under this ICR may include one or more of the following data items, which are included in 40 CFR Part 158, Data Requirements for Pesticide Registration:

1) Monitoring data (PDP, FDA, FSIS, States, special monitoring [market basket, single serving, etc.])
2) Field trials,
3) Processing studies,
4) Reduction in residue data (washing, peeling, cooking, etc.),
5) Livestock feeding studies
6) Metabolism studies
7) Percent crop treated data

SOURCE OF DATA USED IN ANTICIPATED RESIDUES	DATA NEEDED TO CONFIRM ANTICIPATED RESIDUES 5 YEARS LATER
Monitoring data (Pesticide Data Program (PDP), FDA, FSIS, States, special monitoring [market basket, single serving, etc.])	Updated monitoring data are required. The registrant may use any of the publicly available sources used by the Agency. Data should reflect the time period since establishment of the tolerance. If data are not available from the above sources, then the registrant must conduct an appropriately designed monitoring study. The design of this study must be approved by the Agency.
Field trials	The registrant must EITHER verify that the pesticide formulations, application rates, timing, intervals, geographic distribution of use, etc., have not changed OR provide field trial data that reflect any changes in the use pattern that may lead to increased residues.
Processing studies Reduction in residue data (washing, peeling, cooking, etc.)	The registrant must EITHER certify that commercial processing practices have not changed significantly OR provide new processing studies reflecting current commercial practices. A similar requirement applies to any study used to demonstrate reduction in residues between farm gate and consumption.
Livestock feeding studies and metabolism studies	Registrant must EITHER verify that the dietary burden calculations that were incorporated in the original AR derivation for meat, milk, poultry or eggs are still valid OR provide a new animal feeding study that reflects current feeding practices. Dietary burden calculations could change due to increased residue levels on feed items or from changes in the relative abundance or use of a particular feed item over time.

EPA has published guidelines for studies listed in 40 CFR Part 158, Data Requirements. Internal guidelines have also been established for monitoring studies which require a registrant to submit and obtain approval of the study protocol prior to initiating a study. The protocol must describe crops and pesticides to be covered by the study. After approval, the applicant must adhere to the protocol or seek approval for major deviations. SOP No. HED AR-1 contains the specific requirements when ARs are used (see Attachment H).

If EPA relies on ARs data when establishing or reassessing a tolerance, it generally must issue a DCI, and if the EPA used the percent of crop treated data estimates for a tolerance action, it may generally issue a DCI. A DCI is a letter sent to the registrant that explains the data submission requirement, requests specific data, sets out a time frame for a response to EPA, and provides applicable forms and guidelines to assist the registrant with the completion of the DCI request. A registrant must respond within 90 days of receipt of the DCI. The response must describe plans to submit the required data in accordance with the time frame specified, and, if

applicable, contain suggested protocols for monitoring studies. Failure to generate the requested data, or respond to the DCI in a timely manner, could result in Agency action to modify or revoke the tolerance.

There are two main categories of applications for this collection: those requiring submission of a full complement of supporting data, (e.g., new chemicals, and biorationals); and those requiring submission of little or no data, (e.g., "me-too" products) for previously registered chemicals and use patterns. Applicants for a "me-too" product (i.e., a pesticide claimed to be substantially similar in composition and use to a product previously registered by the EPA) may be required only to use EPA Form 8570-34, Certification with Respect to Citation of Data (in Pesticide Registration (PR) Notice 98-5) (Attachment F), and EPA Form 8570-35, Data Matrix (also in PR Notice 98-5) (Attachment G), to certify that the applicant intends to rely on data previously submitted to the EPA by another producer, the applicant has contacted the appropriate company (owning the data that the applicant is referencing), and the applicant has offered to pay reasonable compensation for the use of the data.

(ii). Respondent Activities

A registrant must take the following actions to comply with a DCI:

Read instructions	Read the DCI letter to understand what data are to be submitted;
Plan activities	Plan the activities necessary to comply with the DCI. These may include: a) request a waiver; b) agree to do data; c) certify offer of compensation with original data submitter; d) volunteer to cancel the registration of concern; e) claim a generic data exemption;
Create information	Conduct research, administer tests, analyze data to develop studies, perform and report laboratory analyses;
Gather information	Search for existing data that will satisfy the DCI;
Compile and review	Assemble and evaluate data for accuracy and appropriateness for compliance with the DCI;
Complete paperwork	Prepare necessary correspondence documents and packages for submitting data to EPA; and
Submit and file	Transmit the data and other information to EPA and catalog in company files.

5. THE INFORMATION COLLECTED: AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

The Agency must perform the following actions to conduct a DCI:

Develop DCI notice	Determine data requirements and prepare the DCI letter identifying all data needed and respondent's options; issue DCI;
Answer questions	Respond to any questions the registrant may have regarding the DCI;
Examine responses and data submissions; archive documents	Examine responses and data submissions for acceptability and responsiveness to DCI; if necessary, clarify or seek additional information from registrant; process, catalog and archive DCI data into the Pesticide Document Management System (PDMS); refer non-responders to the Office of Enforcement and Compliance and Assurance for action;
Analyze data	Conduct scientific reviews of the data; and
Record and store DCI data	Record facts of the submission for compliance monitoring and archive in EPA files.

5(b) Collection Methodology and Management

OPP tracks DCIs and all registrant responses through the Office of Pesticide Programs Information Network (OPPIN), OPP's general purpose action tracking system. Additionally, the Reference Files System (REFS) is used if the registrant voluntarily cancels a product in response to a DCI. The Pesticide Data Management System lists the bibliography of data submitters for the DCI and OPPIN tracks the submissions. All correspondence associated with the issuance and response to the DCI is filed in the master registration file or ‘registration jacket’ of affected products. Data submitted in response to a DCI is processed, catalogued and archived in the PDMS. Failures to comply with DCI requirements are referred to EPA's Office of Enforcement and Compliance Assurance for appropriate follow-up actions. Records submitted pursuant to a DCI are subject to Freedom of Information Act (FOIA) requests.

5(c) Small Entity Flexibility

Currently, pesticide registrants may be divided into two groups. Approximately 10 percent of the total: manufacture or import chemical active ingredients intended for use as pesticides, sell these active ingredients to other firms for formulation into pesticide products, and/or make the end-products themselves. The second, and by far the larger, group of registrants purchase the active ingredients in their pesticide products from members of the first group, and combine them with pesticide inert ingredients or sometimes simply repackage them to make their end-use products.

This second group is primarily comprised of small businesses. When small businesses use a

registered source of the active ingredient to formulate their products, they generally are exempt from generating health and safety data for pesticide active ingredients ("generic data"). Consequently, they usually need only respond to a DCI for active ingredient data by claiming the "generic data exemption." They do not incur any other information burden associated with the generic data call-in.

5(d) Collection Schedule

DCIs will generally be issued whenever ARs data is relied upon, either to establish new tolerances or reassess existing tolerances. Registrants have five years before data must generally be submitted in support of the ARs used. Data must also be periodically reviewed when PCT estimates are relied upon, but in most cases the Agency will be able to internally collect or generate this data. In cases where the Agency is unable to get the information itself, the registrant must submit data within five years of the use of PCT estimates. A registrant must respond within 90 days of receipt of the DCI. The response must describe plans to submit the required data in accordance with the time frame specified, and, if applicable, contain suggested protocols for monitoring studies. Additional time is provided for development of new studies appropriate to the nature of the studies required.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

To estimate the burden and costs for the paperwork related activities for the respondents to comply with DCIs that could be issued under this ICR, EPA used the same methodology as was previously used to estimate DCI related paperwork burden. A general description of this methodology is provided in Attachment I. In short, this methodology used the total cost of the test required by the DCI to generate estimates for the burden and cost of the paperwork related activities associated with DCIs. The following estimates represent the burden and costs for the paperwork related activities, and therefore includes the paperwork burden and costs related to the creation and gathering of the data.

6(a) Estimating Respondent Burden

The annual respondent burden for the collection of information associated with this activity is estimated to average between 59 and 13,636 burden hours per DCI, depending upon the type of response requested. The total estimated burden for this ICR of 28,569 burden hours is based on the Agency's estimate of the potential burden and number of responses for each of the following four types of potential DCIs:

1) DCI for anticipated residues requiring a base set of data (13,636 hrs.);
2) DCI for anticipated residues requiring minimum data (69 hrs.);
3) DCI for anticipated residues collected from publically available sources (137 hrs.); and
4) DCI for percent crop treated using existing information (59 hrs.).

The following information presents the Agency's burden estimates for each type of DCI.

DCI Type 1 - DCI for anticipated residues requiring a base set of data:

Respondent burden hours for generating and submitting data in response to a DCI for anticipated residues requiring a base set of data to be submitted are estimated at 13,636 burden hours per response.

EPA also considered the typical burden for reading instructions, planning activities, compiling and reviewing the submission, submitting the data to EPA, and related record keeping in estimating the total per response burden and costs. Using the EPA PDP contracts as the basis, EPA estimated the burden for conducting a monitoring study to gather the necessary data, and the annual respondent cost for meeting 40 CFR part 158 data requirements for anticipated residues. See Table 1.

Since, in most cases, registrants will be able to get the information from federal and state monitoring programs, EPA estimates that no more than 2 registrants might generate their own monitoring data in response to the DCI. The total burden for this type of DCI is therefore estimated to be 27,272 hours per year for two respondents.

TABLE 1 - Annual Respondent Burden/Cost Estimates for Anticipated Residues Generating Anticipated Residue Data

	BURDEN HOURS (per year)			TOTAL	
ACTIVITIES	Mgmt. $130	Tech. $88	Cler. $40	Hours	Costs
1) Read instructions	2	0	0	2	260
2) Plan activities	4	0	0	4	520
3) Create information	0	13,600	0	13,600	1,196,800
4) Gather information	0	16	0	16	1,408
5) Compile and review	1	8	0	9	834
6) Complete paperwork	2	0	2	4	340
7) Maintain and file	0	0	1	1	40
TOTAL	9	13,624	3	13,636	$1,200,202

BURDEN: 13,636 hours x Average of 2 responses = 27,272 Total Burden Hours.

DCI Type 2 - DCI for anticipated residues requiring minimum data:

Minimum data captures the burden for cases in which the respondent verifies that nothing has changed; i.e., the formulation, use rate, geographic distribution of use, etc. have not changed since the ARs where used to establish or reassess the tolerance. Average burden hours per respondent for submitting a base set of data for updating use information is estimated at 69 burden hours per year per response. EPA estimates that no more than 10 respondents each year will comply with a DCI by submitting a base set of data for updating use information. As such, the total respondent burden hours per year are estimated at 690 hours. See Table 2.

TABLE 2 - Annual Respondent Burden/Cost Estimates for Anticipated Residues Requiring Minimum Data

	Burden Hours (per year)			Total	
Collection Activities	Mgmt. $130	Tech. $88	Cler. $40	Hours	Costs
1) Read Instructions	8	0	0	8	1,040
2) Plan Activities	16	0	0	16	2,080
3) Create Information	0	0	0	0	0
4) Gather Information	0	16	0	16	1,408
5) Compile and Review	2	16	0	18	1,668
6) Complete Paperwork	2	0	8	10	580
7) Submit and File	0	0	1	1	40
Total	28	32	9	69	$6,816

BURDEN: 69 hours x Average of 10 responses = 690 Total Hours.

DCI Type 3 - DCI for anticipated residues collected from publically available sources:

The average respondent burden for submitting a base set of data for updating monitoring information is estimated at 137 burden hours per year. EPA estimates that an average of 4 respondents each year are likely to be able to comply with a DCI by submitting data from publically available sources. As such, the total annual respondent burden for this type of DCI is estimated to be 548 burden hours. See Table 3.

TABLE 3 - Annual Respondent Burden/Cost Estimates for Anticipated Residues Collected from Publicly Available Sources

	Burden Hours (per year)			Total	
Collection Activities	Mgmt. $130	Tech. $88	Cler. $40	Hours	Costs
1) Read Instructions	8	0	0	8	1,040
2) Plan Activities	16	0	0	16	2,080
3) Create Information	0	0	0	0	0
4) Gather Information	0	60	0	60	5,280
5) Compile and Review	2	40	0	42	3,780
6) Complete Paperwork	2	0	8	10	580
7) Submit and File	0	0	1	1	40
Total	28	100	9	137	12,800

BURDEN:137 hours x Average of 4 responses = 548 Total Hours.

DCI Type 4 - DCI for percent crop treated using existing information:

The annual per respondent burden for generating percent crop treated estimates using existing information is estimated to be 59 burden hours. Percent crop treated estimates are generally conducted within the Agency, and only in rare instances would a registrant need to gather the information; one per year may be an overestimation. The estimated costs assume that cost of purchasing, or obtaining percent crop treated information derived from existing, contracted data sources. See Table 4.

TABLE 4 - Annual Respondent Burden/Cost Estimates for Percent Crop Treated Using Existing Information

	Burden Hours (per year)			Total	
Activities	Mgmt. $130	Tech. $88	Cler. $40	Hours	Costs
1) Read Instructions	1	1	0	2	218
2) Plan Activities	0	2	0	2	176
3) Create Information	0	8	0	8	704
4) Gather Information	0	22	0	22	1,936
5) Compile and Review	1	20	0	21	1,890
6) Complete Paperwork	1	0	2	3	210
7) Submit and File	0	0	1	1	40
Total	3	53	3	59	$5,174

BURDEN: 59 hours x average of generating 1 response = 59 Total Hours

6(b) Estimating Respondent Costs

The corresponding estimated respondent cost for this collection is $2,524,938. Respondent costs are based on managerial, technical and clerical burden hours estimated at $130, $88, and $40 per hour, respectively. EPA has calculated the estimated labor rates for respondents to the requirements of this ICR factoring in an inflation cost index of 1.056 based on the Gross Domestic Product. These labor rates are fully loaded and include benefits and overhead costs.

The total estimated cost for this collection is based on the Agency's estimate of the *potential cost* and *number of responses* for each of the following four types of potential DCIs:

1) DCI for anticipated residues requiring a base set of data - $2,400,404
2) DCI for anticipated residues requiring minimum data - $68,160
3) DCI for anticipated residues collected from publically available sources - $51,200; and
4) DCI for percent crop treated using existing information - $5,174.

6(c) Estimating Agency Burden and Costs

Annual Agency burden for managing individual information from Type 1, 2 or 3 DCIs is estimated at 99 burden hours per response. The hourly rates are $96, $70, and $33 per hour for management, technical, and clerical staff, respectively. Agency labor rates are based on Office of Personnel Management salary tables for federal employees for the years 1999 through 2001 and include benefits and overhead costs, as well as locality pay for the Washington, DC-Baltimore area. The annual Agency cost for managing an individual response is estimated at $6,501 per response.

Since the average number of responses each year for these DCIs is estimated to be 16, the total annual burden for the Agency activities is estimated to be 1,584 burden hours, with an associated cost of $104,016 per year. See Table 5.

TABLE 5 - Annual Agency Burden/Cost Estimates for Processing DCI Types 1-3

	Burden Hours (per year)			Total	
Collection Activities	Mgmt. $96	Tech. $70	Cler. $33	Hours	Costs
Develop DCI notice	1	0	2	3	162
Answer Registrants' questions	0	4	5	9	445
IN-process data submissions	0	0	4	4	132
Analyze data	1	80	0	81	5,696
Record and store DCI data	0	0	2	2	66
Total	2	84	13	99	$6,501

BURDEN: 99 hours x 16 responses = 1,584 Total Hours
COSTS: $ 6,501 x 16 responses = $104,016 Total Costs

The annual Agency burden for managing individual DCI information for percent crop treated is estimated at 59 hours per response, with an estimated cost of $3,701 per response. Since the Agency estimates no more than 1 response each year, if any, the total annual Agency burden and cost is 59 burden hours, and $3,701 See Table 6.

TABLE 6 -Annual Agency Burden/Cost Estimates for Processing DCI Type 4

	Burden Hours (per year)			Total	
Collection Activities	Mgmt. $96	Tech. $70	Cler. $33	Hours	Costs
Develop DCI notice	1	0	2	3	162
Answer Registrants' questions	0	4	5	9	445
IN-process data submissions	0	0	4	4	132
Analyze data	1	40	0	41	2,896
Record and store DCI data	0	0	2	2	66
Total	2	44	13	59	$3,701

BURDEN: 59 hours x 1 response = 59 Total Hours
COSTS: $3,701 x 1 responses = $3,701 Total Costs

6(d) Bottom Line Burden Hours and Cost Table

The total estimated annual respondent burden is 28,569 burden hours (28,509 burden hours for all AR DCI submissions + 59 burden hours for Percent Crop Treated DCI submissions), with an associated cost of $2,524,938 ($2,519,764 for all AR DCI submissions + $5,174 for Percent Crop Treated DCI submissions). See Table 7.

The total estimated annual Agency burden is 1,643 burden hours (1,584 burden hours for all AR DCI submissions + 59 burden hours for Percent Crop Treated DCI submissions), with an associated cost of $107,717 ($104,016 for all AR DCI submissions + $3,701 for Percent Crop Treated DCI submissions).

	Key Activities	Hours	Costs
Respondents	Total respondent burden/costs for generating anticipated residue data.	27,272	$2,400,404
	Total respondent burden/costs for submitting minimal anticipated residue data.	690	$68,160
	Total respondent burden/costs for submitting anticipated residue data from publicly available sources.	548	$51,200
	Total respondent burden/costs for submitting percent crop treated data using existing information.	59	$5,174
Total estimated respondent burden/costs.		28,569	$2,524,938
Agency	Total Agency burden/costs for managing anticipated residue DCI's	1,584	$104,016

	Total Agency burden/costs for managing percent crop treated DCI's.	59	$3,701
Total Agency burden/costs.		1,643	$107,717

6(e) Reasons for Change in Burden

In the previous ICR, OMB approved 29,807 burden hours, with a cost of $2,773,866. This ICR renewal request reflects a decrease of approximately 1,238 burden hours for an annual respondent burden of 28,569 hours and a decrease in cost of $248,928, for an annual respondent cost of $2,524,938. These reductions are adjustments due to the fact that the Agency expects to issue fewer data call-ins under this program than originally estimated. Oftentimes, data can be acquired more efficiently without issuing a DCI. For example, OPP works closely with USDA's Pesticide Data Program (PDP) which generates publically available monitoring data. OPP can get the PDP monitoring data more quickly and in a format most usable to the Agency by requesting the data directly from USDA. This would eliminate the cost to the pesticide registrants and would save the Agency time and the administrative expense associated with a data-call-in. Similarly, data on changes in processing practices that may lead to increases in residues can more efficiently collected in cooperation with food industry associations. Also, in many cases the Agency can continue to stand by its safety finding without requiring additional data because the risk is so low that even large increases in exposure would not create a risk of concern.

6(f) Burden Statement

The total annual respondent burden for this ICR is estimated to be 28,569 hours, ranging from 59 hours to 13,636 hours per response, depending on the type of DCI.

According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

To comment on EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID No. OPP-2004-0109, which is available for public viewing at the OPP Docket in the Public Information and Records Integrity Branch, Rm. 119, Crystal Mall #2, 1801 Bell Street., Arlington, VA. This docket facility is open from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

An electronic version of the public docket for this ICR renewal is available through EDOCKET at

http://www.epa.gov/edocket. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID No. OPP-2004-0109 and OMB Control No. 2070-0164 in any correspondence.

ATTACHMENTS TO THE SUPPORTING STATEMENT

ATTACHMENT A: FFDCA Section 408(b) - Included in the electronic file for this ICR and also available electronically at http://www.epa.gov/epahome/laws.htm.

ATTACHMENT B: FIFRA Section 3(c)(2)(B) - Included in the electronic file for this ICR and also available electronically at http://www.epa.gov/oppfead1/fqpa/ and click on "LAWS," then click on the available PDF file for FIFRA.

ATTACHMENT C: Data Call-In Response Form. A pdf copy is available electronically through EDOCKET.

ATTACHMENT D: Requirements Status and Registrant's Response Form. A pdf copy is available electronically through EDOCKET.

ATTACHMENT E: Certification of Attempt to Enter into an Agreement with Registrants for Development of Data (EPA Form 8570-32). A pdf copy is available electronically through EDOCKET and is also available electronically at http://www.epa.gov/opprd001/forms/8570-32.pdf

ATTACHMENT F: Certification with Respect to Citation of Data (EPA Form 8570-34). A pdf copy is available electronically through EDOCKET and is also available electronically at http://www.epa.gov/opprd001/forms/8570-34.pdf

ATTACHMENT G: Data Matrix (EPA Form 8570-35). A pdf copy is available electronically through EDOCKET and is also available electronically at http://www.epa.gov/opprd001/forms/8570-35.pdf

ATTACHMENT H: SOP No. HED AR-1, Use of Anticipated Residues in Risk Assessment. Included in the electronic file for this ICR.

ATTACHMENT I: Estimating the Potential Paperwork Burden and Cost for DCIs. Included in the electronic file for this ICR.

ATTACHMENT J: Consultation Contacts for Data Generation for Pesticide Reregistration Programs; EPA Questions Asked in Consultations**.** Included in the electronic file for this ICR.

ATTACHMENT K: Comments received in to the Consultation Process; EPA Response to Specific Consultation Comments. Included in the electronic file for this ICR.

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164 EPA No. 1911.02

Attachment A

Federal Food, Drug, and Cosmetic Act (FFDCA)
Section 408(b) - Authority and Standard for Tolerance

Attachment A - FFDCA § 408(b)

Authority and standard for tolerance

(1) Authority

The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food -

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) Standard

(A) General rule

(i) Standard

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) Determination of safety

As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) Rule of construction

With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) Tolerances for eligible pesticide chemical residues

(i) Definition - As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which -

(I) The Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) Determination of tolerance - Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this

subparagraph if -

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) Conditions regarding use - For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) Conditions regarding risk - For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) Review - Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

(vi) Infants and children - Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) Exposure of infants and children

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator -

(i) shall assess the risk of the pesticide chemical residue based on -

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall -

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) Factors

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors -

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E) Data and information regarding anticipated and actual residue levels

(i) Authority

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) Requirement

If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) of this section require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1) of this section, or an order under subsection (f)(2) of this section, as appropriate, to modify or revoke the tolerance.

(F) Percent of food actually treated

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator -

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) Detection methods

(A) General rule

A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) Detection limit

A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) International standards

In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164; EPA No. 1911.02

Attachment B

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
FIFRA Section 3(c)(2)(B)

FIFRA Section 3(c)(2)(B) – Data in Support of Registration.--

(A) In General.-- The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment.

The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this Act, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) Additional Data.--(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required.

Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification.

Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall

share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this Act, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 4 for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996, if –

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 4; and

(IV) the Administrator has determined that based on existing data, such extension would

not significantly increase the risk of any unreasonable adverse effect on the environment.[1] If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as the date of enactment of the Food Quality Protection Act of 1996, for the submission of data under section 4 for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii) (I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out

[1] Indentation of the following sentences of this clause is so in original (as added by sec. 201(c)(1) of P.L. 104-170). Probably should be indented to the same as flush matter of this clause.

subclause (I).

(III) Not later than 1 year after the date of enactment of this clause, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified Procedures.-- Within nine months after the date of enactment of this subparagraph, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption.--No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to–

(i) submit or cite data pertaining to such purchased product; or
(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor Use Waiver.--In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining--

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070- 0164 EPA No. 1911.02

Attachment C

Data Call-in (DCI) Response Form

[A electronic copy is available through EDOCKET.]

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164 EPA No. 1911.02

Attachment D

Requirements Status and Registrant's Response Form

[A electronic copy is available through EDOCKET.]

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164 EPA No. 1911.02

Attachment E

Certification of Attempt to Enter into an Agreement with Registrants for Development of Data (EPA Form 8570-32)

[A electronic copy is available through EDOCKET.]

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164 EPA No. 1911.02

Attachment F

Certification with Respect to Citation for Data (EPA Form 8570-34)

[A electronic copy is available through EDOCKET.]

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164 EPA No. 1911.02

Attachment G

Data Matrix (EPA Form 8570-35)

[A electronic copy is available through EDOCKET.]

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164 EPA No. 1911.02

Attachment H

SOP No. HED AR-1, Use of Anticipated Residues in Risk Assessment

1.0 Purpose

To standardize the procedures used by scientists in the Health Effects Division for calculation of anticipated residues.

2.0 Scope

This procedure shall be followed by all HED personnel involved in the manipulation of data to calculate anticipated residues to be used in risk assessment estimates.

3.0 Outline of Procedures

- Regulatory Background
- Interpretations of FFDCA
- Definition of Terms Used in this Document
- Dietary Exposure
- Data Needed to Verify Anticipated Residues
- Non-Detects
- Documentation Requirements

4.0 References

- Federal Food, Drug, and Cosmetic Act (FFDCA)
- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Food Quality Protection Act (FQPA)
- Residue Chemistry Guidelines OPPTS 860.1500, 860.1520
- Acute Dietary Exposure Assessment OPP Policy, June 1996
- Chronic Dietary Exposure Assessment OPP Policy, ??? 1997
- Chemistry Science Advisory Council (CHEM SAC) Decisions

5.0 Specific Procedures

5.1 Regulatory Background

Section 408(b)(2)(E) of FFDCA as amended by FQPA requires that if EPA relies on **anticipated residues (ARs) or Actual Residues** to establish, modify, or leave in effect a tolerance, then EPA must require that data be provided five years after the tolerance decision is made to demonstrate that such residue levels have not changed.

Section 408(b)(2)(F) of the Act states that the Agency may use data on the actual percent of food treated or "**percent crop treated"** (PCT) in chronic dietary risk if such data are reliable and its use will not understate exposure for any significant population subgroup.

Section 408(f) of FFDCA "Special Data Requirements" states that if EPA requires additional data

or information to support a tolerance or exemption, it shall issue (a) a DCI, (b) a rule requiring testing or (c) an order in the FR.

5.2 Interpretations of FFDCA

5.2.1 **408(b)(2)(E)**--If EPA relies on anticipated or actual residue levels in establishing, modifying or leaving in effect a tolerance, it must call in data within five years **for all crops for which AR's were used** for a pesticide. Such data will be used to demonstrate that the residue levels are not above the (anticipated) levels relied on. If the residues are higher, EPA shall reassess the risk posed by the pesticide and modify or revoke the tolerance as required to assure no adverse health concerns result from the pesticide.

5.2.2 **408(b)(2)(F)**--Whenever PCT has been used, EPA will obtain data through its usual sources (i.e., BEAD) within five years and determine whether the risks have increased unacceptably. EPA will not issue a data-call-in (DCI).

5.2.3 **408(f)**--EPA may use three methods to require data, but will use DCIs.

No rule is required for implementation of these provisions of the Act, but an Information Collection Request (ICR) covering the AR DCI data must be cleared through the Office of Management and Budget (OMB) before DCIs can be issued. A PR Notice will be issued to notify registrants and the public about FQPA's requirements on AR/PCT and the process the Agency will follow.

5.2.4 FIFRA Section 18 Tolerances--Any tolerances established in conjunction with FIFRA Section 18s that use ARs and/or PCT are subject to FQPA. Data or information required to verify these tolerances are required to be submitted five years after their issuance unless EPA obtains and uses new information that either corroborates or changes the initial AR data. If a Section 18 tolerance is repeatedly renewed with little or no new information, data must be called in.

To obtain AR data for Section 18 exemptions, OPP may: (a) issue a letter requesting data from the main registrant (producer of the technical) at the same time that the Section 18 is issued; (b) place a notice in the initial Section 18 approval telegram (and in subsequent years) indicating that data are required to be submitted five years later or else a Section 18 will not be granted and the tolerance will be revoked (registrants would also be notified by letter of this requirement); or (c) both.

5.3 Definition of Terms Used in this Document

5.3.1 **Anticipated Residues** are estimates of the level of residues of a pesticide likely to be present on a given crop and are generally lower than tolerances. Data used for these estimates are based on:

1) *Field Trial Studies* designed to show what residue levels will be present in crops at harvest. These studies are conducted at maximum label rate and minimum pre-harvest interval, and are designed to show the maximum residues likely to be present. Field trial data can be used to project the residue amounts on treated crops and how various factors may affect those levels. Field trial data can therefore, be combined with percent crop treated data to produce a more realistic estimate of human exposure.

2) *Monitoring Data* which provide measurements of actual residues in/on commodities as they move in commerce. Monitoring data or actual residue data are collected by sampling a cross-section of a crop and it include treated and untreated commodities. Actual residue data reflects both the processes measured by field trial studies and the percent of the crop actually treated. Therefore, actual residue data for a given commodity would generally not be combined with either field trials data or percent crop treated information for that commodity in estimating human exposure. Actual residue measurements are taken on samples gathered as the commodities leave the farm (e.g., FDA Surveillance samples taken as close as possible to the point of production), when the food is in the general channels of distribution (e.g., USDA's PDP taken at food distribution centers), or at the retail level (e.g., EBDCs market basket survey). Actual residues are provided by:

a) FDA Programs--Surveillance/Compliance Monitoring and Total Diet.
b) USDA Programs– AMS Pesticide Data Program and FSIS Monitoring Program (meat and poultry).
c) Special Studies--FDA Total Diet Survey which show residues after consumer preparation or cooking of foods.

3) *Processing Studies* designed to determine the concentration or reduction of residues when the raw agricultural commodity is processed commercially.

4) *Degradation/Decline Studies* showing the degradation rates of pesticide residues.

5) *Livestock Feeding Studies and Nature of the Residue in Livestock* to identify the nature of the residue in the edible tissue of livestock and the transfer of these residues to meat, milk, poultry, and eggs. These studies are required when a pesticide is applied directly to livestock, to crops or crop parts used for feed, or when livestock premises are to be treated.

5.3.2 **Percent Crop Treated** means the scope of pesticide treatment for a crop expressed as a percentage. Percent crop treated information is useful for estimating exposure because it defines what segment of the crop is pesticide free.

5.4 Dietary Exposure

Dietary exposure to pesticides in foods is estimated by multiplying the daily consumption of the food forms of a given commodity by the amount of pesticide residues on the food forms. Exposures based on tolerance levels are Theoretical Maximum Residue Contribution (TMRC)

estimates. A TMRC is considered a "worst case" estimate because it assumes that the food contains residues at the tolerance level and that 100 percent of the crop is treated. If the TMRC exceeds the reference dose or poses an unacceptable lifetime cancer risk, EPA attempts to derive a more accurate estimate of residues likely to be present in foods (anticipated residues).

5.4.1 **Tiered Approach to Estimating Dietary Exposure**: In an attempt to conserve resources, the Agency developed a tiered process by which pesticide tolerance data (40 CFR 158.240) are refined to reflect pesticide residues in food as consumed (dinner-plate). This tiered approach flows from conservative to more refined assumptions as the risk management situation dictates. Dietary exposure estimates based on tolerance level residues (farm-gate) reflect a Theoretical Maximum Residue Contribution (TMRC) which overestimate actual dietary exposure. The best estimate of pesticide residues in food, as consumed, is termed the Anticipated Residue (AR) estimate. When estimating ARs the Agency uses all available data, therefore, reviewers must exercise considerable scientific judgment to derive anticipated residue estimates.

Attachment 1 summarizes applicability of the various tiers in estimating acute and chronic exposures.

5.5 Data Needed to Verify Anticipated Residues

Verification of the anticipated residues used in establishing a tolerance depends on the data source. Table 1 below addresses specific cases.

Table 1. Data Needed to Verify Anticipated Residue Calculations

SOURCE OF DATA USED IN ANTICIPATED RESIDUES	**DATA NEEDED TO CONFIRM ANTICIPATED RESIDUES 5 YEARS LATER**
Monitoring data (PDP, FDA, FSIS, States, special monitoring [market basket, single serving, etc.])	Updated monitoring data are required. The registrant may use any of the publicly available sources used by the Agency. Data should reflect the time period since establishment of the tolerance. If data are not available from the above sources, then the registrant must conduct an appropriately designed monitoring study. The design of this study must be approved by the Agency.
Field Trials	The registrant must EITHER verify that the pesticide formulations, application rates, timing, intervals, geographic distribution of use, etc., have not changed OR provide field trial data that reflect any changes in the use pattern that may lead to increased residues.
Processing studies Reduction in residue data (washing, peeling, cooking, etc.)	The registrant must EITHER certify that commercial processing practices have not changed significantly OR provide new processing studies reflecting current commercial practices. A similar requirement applies to any study used to demonstrate reduction in residues between farm gate and consumption.

Livestock feeding studies and metabolism studies	Registrant must EITHER verify that the dietary burden calculations that were incorporated in the original AR derivation for meat, milk, poultry or eggs are still valid OR provide a new animal feeding study that reflects current feeding practices. Dietary burden calculations could change due to increased residue levels on feed items or from changes in the relative abundance or use of a particular feed item over time.

5.5.1 **Hypothetical Scenario**: A tolerance is established for a chemical already registered for use on ten food crops. Anticipated residues are developed for seven of ten previously registered crops to support registration of crop 11 as shown in Table 2.

Table 2. Data Sources Used to Support the Tolerance for "New Crop 11

TOLERANCES	DATA SOURCE	RESIDUE ESTIMATE	ANTICIPATED RESIDUE?
Old crop 1	Monitoring	Mean	Yes
Old crop 2	Monitoring	Mean	Yes
Old crop 3	Monitoring	Mean	Yes
Old crop 4	Monitoring	Mean	Yes
Old crop 5	Monitoring	Mean	Yes
Old crop 6	Field trials	Mean	Yes
Old crop 7	Field trials	Mean	Yes
Old crop 8	Field trials	Tolerance	No
Old crop 9	Field trials	Tolerance	No
Old crop 10	Field trials	Tolerance	No
estimated residue consumption from crops 1-10 = 80% of RfD			
New crop 11	Field trials	Tolerance	No
estimated residue consumption from crops 1-11 = 90% of RfD			

In accordance with the interpretation in Section 5.2 above, the registrant has to verify that the ARs on crops 1 through 7 still support the tolerance on crop 11 after 5 years. Each individual AR for crops 1 through 7 must be confirmed with data similar to that originally used to derive the AR for that crop (see Table 1). This confirmation will be on a crop by crop basis. If the anticipated residue for any commodity exceeds the value relied on previously then a new dietary risk assessment will be necessary to determine if the tolerance on crop 11 needs to be altered or revoked.

5.6 Non-Detects

There are two possible explanations for residues reported as "not detected": either the residues are for all practical purposes zero (e.g., pesticide was not applied) or the residues may be present at levels lower than the limit of detection (LOD) of the analytical method used. The Chem SAC recommendations for handling non-detects are as follows:

1. A true zero may be entered for non-detects if the percentage of samples reported as non-detects is equal or greater than the percent crop *not* treated. The number of samples entered as zeros should be directly proportional to the percent crop *not* treated. The reviewer should work closely with BEAD in selecting the appropriate percent crop treated figure (e.g., maximum, average, or other PCT figure).

2. A zero may be used to represent non-detects if metabolism studies, data at shorter PHIs, exaggerated rate data, etc. support this decision.

3. A value such as ½ LOD or ½ LOQ or the Lower Limit of Method Validation (LLMV) may be used. [LLMV: lowest concentration at which the method was validated. A LLMV could be higher than true LOQ.]

5.7 Documentation Requirements

Estimation of anticipated residues must be thoroughly documented. All HED documents transmitted to RD or SRRD that are concerned with either establishing, modifying, or leaving in effect a tolerance must contain the following information:

a. **Percent Crop Treated (PCT)**: Indicate whether assumption of 100 percent crop treated is made or actual percent crop treated data were used. If PCT data were used, include the source of these data (e.g., for BEAD data, attach transmittal memorandum documenting years the PCT represent for each crop). Describe any assumptions made and actual PCT values used.

b. **Dietary Exposure Assessment:** Must contain a clear and complete account of the basis for estimating dietary exposure. For each food form included in the assessment, indicate whether exposure was based on tolerance level residues or anticipated residues and whether PCT data were used.

c. **Anticipated Residues:** If ARs were used, list actual numerical estimates used and the source of the estimate (i.e., FDA monitoring data, field trial data, processing studies, etc.) Document must fully describe all values, assumptions, and data manipulation used in deriving anticipated residues including use of default values (e.g., ½ LOD/LOQ for non-detects, ½ LOQ for BQLs, etc.). The sources of all data must be documented sufficiently that any interested party could repeat the calculations.

   The HED recommended format for documentation of anticipated residues derived from field trials, monitoring data, and processing studies is provided in examples given in Attachment 2.

d. **Dietary Exposure Assessments:** Must be documented in the form of a memorandum containing all of the elements found in the HED DEEM SOP (being prepared by DRES committee). Each memorandum will contain, at a minimum, a description of the following information:

a. Type of action (section 18, reregistration, new use, etc.).
b. Toxicological Information (RfD, data gaps, uncertainty factor, NOEL, carcinogenicity, etc), including reference to HED documents containing these data.
c. Residue Information (CFR references, PCT, AR data, concentration factors, etc.) including reference to HED documents containing these data.
d. Results and Discussion (refinements to the analysis, TMRC and ARC numbers, changes to concentration factors, population subgroups exceeding 100% RfD, commodity contribution analysis if RfD exceeds 100%.
e. Names of preparer and reviewer, date, and file location.
f. For Monte Carlo runs attach input and output files.

Attachment 1

Tiered Approach to Estimating Dietary Exposure *

	Dietary Assessment		
	Acute		Chronic (Carcinogenic and non-carcinogenic)
	Single Serving	Blended	Single Serving/Blended
Tier 1	▹Tolerance ▹100% CT	▹Tolerance ▹100% CT	▹Tolerance ▹100% CT
Tier 2	▹Tolerance ▹100%CT	▹Average residue from field trials ▹100% CT	▹Tolerance ▹Adjust for %CT
Tier 3	▹Entire distribution of data from field trials ▹Adjust for %CT	▹Average residue from field trials ▹Adjust for %CT ▹Processing factors -or- ▹Entire distribution of monitoring data ▹100 %CT. ▹Processing factors	▹Average residue from field trials ▹Adjust for %CT ▹Processing factors -or- ▹Average residue of monitoring data ▹Adjust for %CT ▹Processing factors
Tier 4	▹Single Serving Market basket survey ▹Cooking ▹Residue decline ▹Residue degradation	▹Use monitoring data directly ▹Cooking ▹Residue decline ▹Residue degradation	▹Single Serving Market basket survey ▹Cooking ▹Residue decline, ▹Residue degradation

* For meat, milk, poultry, and eggs, if monitoring data are not available, 1) calculate the dietary burden using anticipated residues for feedstuffs; 2) extrapolate from livestock feeding studies

XYZ (Chemical # 000001)--Anticipated Residues Derived from Monitoring Data

Commodity	Data Source	No. of Samples	No. of Detects	% Detects	LOD ppm	LOQ ppm	% Crop Treated	Max. Residue	Average Residue	95th Percentile
caneberries blackberries boysenberries dewberries loganberries raspberries	FDA 92-96	158	19	12		0.02	55	0.204	0.0089	0.02
blueberries	FDA 92-96	176	10	5.7		0.02	80	0.08	0.0093	T
cranberries	FDA 92-96	69	1	1.4		0.02	7	0.02	0.0008	ND
	FODC 92-96	111	0	0.0		0.02	7	ND		ND
grapes	PDP 95-96	1215	0	0.0		0.023	1	ND	0.0001	ND
strawberries	FDA 92-96	644	78	12.1		0.02	28	0.28	0.0133	0.08

XYZ (Chemical # 000001)--Anticipated Residues Derived from Monitoring Data (continued)

Commodity	Data Source	No. of Samples	No. of Detects	% Detects	LOD ppm	LOQ ppm	% Crop Treated	Max. Residue	Average Residue	95th Percentile
grapefruit	FDA 92-96	133	0	0.0		0.02	1	ND	0.0001	ND
orange	PDP 95-96	1209	6	0.5		0.037	1	0.028	0.0002	ND
orange juice	PDP 97	604	0	0.0		0.02	1	ND	0.0001	ND
apple	PDP 95-96	1723	0	0.0		0.037	15	ND	0.003	ND
apple juice	PDP 96	177	1	0.6		0.023	15	<0.017	0.002	ND
tomatoes	PDP 96	174	0	0.0		0.030	2	ND	0.0003	ND
whole grain wheat	PDP 95-96	940	275	29.3		0.01	100	2.874	0.065	0.305
wheat flour	FDA 92-96	113	79	69.9		0.02	100	1.056	0.0631	0.247
milk	PDP 96	558	0	0.0		0.0033	--	ND	0.0017	ND

XYX (Chemical # 000001)--Anticipated Residues Derived from Field Trial Studies

Crop	Average Residue	Maximum Residue	PCT	Anticipated Residue	Source of Data	Review Reference
Macadamia nuts	0.05	0.1	6	0.00300	MRID 44076801	DP Barcode
Chestnuts	0.261	0.632	100	1.00000	MRID 44478401	DP Barcode
Walnuts	0.05	0.10	9	0.00450	MRID 44383301	DP Barcode
Figs	0.203	0.387	6	0.01220	MRID 44061201	DP Barcode
Guava	0.159	0.48	100	0.15900	MRID 44391501	DP Barcode
Passion Fruit	0.0564	0.121	100	0.05640 or 8??	MRID 44472801	DP Barcode

XYZ (Chemical # 000001)--Anticipated Residues Reflecting Processing Factors

Crop	Processed Form	Concentration or Dilution Factor	Source of Data	Review Reference
Grapes	Juice	0.1X	MRIDXXXXXXX	DP Barcode
	Raisins	0.4X	MRIDXXXXXXX	DP Barcode
Citrus Fruits	Juice	0.06X	MRIDXXXXXXX	DP Barcode
Apples	Juice	0.13X	MRIDXXXXXXX	DP Barcode
Tomatoes	Juice	0.03X	MRIDXXXXXXX	DP Barcode
	Puree	0.6X	MRIDXXXXXXX	DP Barcode
	Catsup	0.8X	MRIDXXXXXXX	DP Barcode
Rice	Milled	0.02X	MRIDXXXXXXX	DP Barcode
Corn	Oil	0.01X	MRIDXXXXXXX	DP Barcode
Cottonseed	Oil	0.007X	MRIDXXXXXXX	DP Barcode
	Meal	0.07X	MRIDXXXXXXX	DP Barcode
Mint	Oil	12.7X	MRIDXXXXXXX	DP Barcode

Methidathion (PC Code 100301)--Anticipated Residues Derived from Monte Carlo Assessments

Crop/Food Form	Data source	# of Samples	PCT	Residues found (Total non-zeros)	Total zeros	Value Entered for NDs	Comments
orange juice	PDP-1997	692	100	10	--	--	
apples	PDP-1998	100	3	3	97	½ LOQ	
pears	PDP-1997	100	11	11	89	½ LOQ	
apple juice	PDP- 1997	683	100		--	½ LOQ	
apple juice	PDP -1996	177	100				
olives	FDA?	2	2	2	98	½ LOQ	
oranges	Field trial	11	11	11	89	--	MRID# 44491001 also used for citron & kumquats maximum value 3.4 ppm

Food Form (RAC/Processed)	year/ data source	# of data points	Conc. Range	Average	Tolerance/ food/feed additive	# of non-detects	LOD	LOQ	Data Handling
grapefruit	1996/field trials	10	0.76-3.76	1.55	4				
dried pulp					8				

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164 EPA No. 1911.02

Attachment I

Estimating the Potential Paperwork Burden and Cost for DCIs

ATTACHMENT I

Estimating the Potential Paperwork Burden and Cost for DCIs

The following is a general description of the methodology used by the Agency to estimate the potential paperwork burden and costs for respondents to comply with data call-ins (DCIs) issued by EPA. In general, the ICRs provided an estimate of the potential paperwork burden and costs related to a typical or general DCI based on sample DCIs derived from previously issued DCIs. Prior to issuing a specific DCI, pursuant to the terms of clearance for the ICRs, EPA calculated the paperwork burden and costs related to the specific DCI using the general method described here.

The estimates represent the burden associated with completing multi-year studies and submitting the study results to EPA in response to a DCI. A portion of the total cost for a study conducted in response to a DCI may be attributed to the paperwork related requirements that EPA imposes on the pesticide registrants. The potential number of DCIs that might be issued in any year, the type of data requested, and the number of respondents potentially affected by a particular DCI vary, and remain unknown until the Agency identifies the need for the information. To help estimate potential burden under these circumstances, EPA reviewed previously issued DCIs to develop sample DCIs that are used to generate burden and cost estimates for the anticipated testing that would be requested by EPA, from which EPA also calculates the paperwork burden and costs.

1. What activities are included in the estimated paperwork burden and cost for DCIs?

Under the Paperwork Reduction Act (PRA) , 44 USC 3501 *et seq.*, and the implementing regulations at 5 CFR 1320 *et seq.*, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This typically includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

In the case of DCIs, a responding Registrant may be required to engage in one or more of the following paperwork related activities:

1) Read DCI & test requirements (includes review of records for previously unavailable data & requesting exemptions or waivers)
2) Discuss test and protocol with Agency
3) Plan activities necessary to respond to DCI
4) Create & gather information (conduct tests)
5) Process, compile, review information for accuracy
6) Complete written forms

7) Submit information to EPA

8) Store, file, or maintain information

OPP will only issue a DCI for a pesticide chemical after it reviews the available data and determines that the available information is not sufficient to satisfy the statutory requirements for reregistration. Although the Agency is responsible for identifying available data, the registrant may have data that is not generally available. In such a case, the registrant may respond to a DCI by simply submitting such data to EPA. In addition, even after OPP has completed its review and has determined that additional data must be called-in, registrants may also request a waiver if they believe that OPP can properly evaluate the risks of their pesticide chemicals without additional data. OPP will review each waiver request individually. For purposes of estimating the potential paperwork burden and costs, EPA assumes that registrants do not have any such data, and that registrants will not request any waivers. Since such activities are likely to be few, the estimates provided will cover these activities and will generally result in an over-estimate of the total burden and costs if these activities occur for any specific DCI.

2. How did EPA estimate the potential Respondent paperwork burden?

In general, the estimates for the total burden and costs associated with a Pesticide Registrant responding to a DCI are derived from the total costs for doing the tests that might be required based on the sample DCIs. The average potential test costs were derived using cost information for individual DCIs previously conducted by the Agency. Based on the cost information available, the Agency calculates an average total test cost for the sample DCIs. These costs then form the basis for calculating the labor costs from which the burden hours are derived.

The Agency anticipates that multiple respondents for a given chemical will establish consortiums to share in the burden of generating the data and that the burden and cost will be distributed proportionately across the participating members of that consortium. However, for purposes of this ICR, EPA estimates are on a per-registrant basis, without considering this possibility for sharing the burden.

Basically two types of respondent burden are considered in deriving the burden estimates: **Administrative Burden** and **Technical Burden**. The respondents' Administrative Burden is defined as the time spent communicating and working with the Agency to develop and agree upon data requirements, the protocol, the field site, and data presentations, and includes the time for registrants to draft and summarize the results of studies completed by an individual respondent or by a consortium of respondents for one chemical. The Administrative Burden is also intended to include time spent overseeing any contractor activities employed by the respondent. The Technical Burden represents the labor needed to actually derive the data, which involves designing the test, performing it, analyzing and compiling test data and summarizing the results.

To derive the **Administrative Burden**, the Agency estimated the amount of administrative labor cost that would be in addition to the total test cost using a percentage of the total test costs. The Agency assumed that respondents would expend approximately two percent of the total cost

for Administrative Burden.[2] The Agency assumed that the value of this time is divided proportionally among management (20%), technical staff (65%) and clerical (15%).[3] The value of labor per hour for management, technical, and clerical is $130, $88, and $40, respectively.[4] The hourly rate includes overhead and benefits. The combination of the proportional distribution of cost across the labor mix and the hourly rate for the labor categories are then used to determine the total burden hours from the total labor cost estimate.

To derive the **Technical Burden**, the Agency assumes that one-third of the total test cost represents labor.[5] Management, technical, and clerical comprise the labor staff. The same proportional labor rate approximations and hourly rates are used to calculate the distribution of hours across the labor mix from the total labor cost estimate.

Since it is anticipated that actual DCI requests per year will vary, the annual estimated burden and costs is distributed evenly across the three year duration of the ICR to estimate an average annual burden and cost.

3. How did EPA estimate the potential Respondent paperwork cost?

As was the case for the burden hour analysis discussed above, two types of costs to respondents are considered for developing the cost associated with this ICR: **Administrative Cost** and **Technical Cost**. The definitions of these costs are the same as those defined for the burden hours with the exception that they are costs not hours. The Administrative Costs are estimated as approximately two percent of the total test cost and are considered additive costs, while the Technical Costs are based on the assumption that one-third of the total test cost represents labor cost.[6] The value of labor is divided proportionally among management (20%), technical staff (65%) and clerical (15%). The value of labor per hour for management, technical, and clerical is $130, $88, and $40, respectively.

The Agency also anticipates that multiple respondents for a given chemical will establish consortiums to share in the burden of generating the data and that the burden and cost will be distributed proportionately across the participating members.

---

[2] This percentage represents an estimate obtained from expert opinion, industry sources, and proprietary data.

[3] This estimate was derived from an assessment of the test data cost estimates by DPRA, Inc.; subcontract with W.R. Landis Associates, Inc.

[4] The hourly rates are based on EPA's 1993 RIA supporting the proposed plant pesticide rule (published in the Federal Register, of March 28, 1994, indexed to 1996 dollars.

[5] Same as Footnote 2.

[6] Same as Footnote 2.

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070-0164 EPA No. 1911.02

Attachment J

Consultation Contacts for Data Generation for Pesticide Reregistration Programs; EPA Questions asked in Consultation

ATTACHMENT J

Data Acquisition for Anticipated Residue and Percent of Crop Treated (OMB 2070-0164)
Consultation Contacts for Data Generation for Pesticide Reregistration Programs

Registrant Associations

Ray McAlister, Vice President — 202-872-3874
Science and Regulatory Affairs
CropLife America
Suite 400
1156 15th Street N.W.
Washington, DC 20005

Susan Little, Executive Director — 202-833-7315
Consumer Specialty Products Association
900 17th Street N.W.
Suite 300
Washington, DC 20006

Registrants

Chris Wible, Manager of Regulatory Issues — 937-644-7012
The Scotts Company
14111 Scottslawn Road
Maryville, OH 43041

Eric Mauer, Federal Registration Manager — 202-872-4682
Valent U.S.A. Corporation
1101 14th Street N.W.
Washington, DC 20005

John Cummings, Manager of Regulatory Affairs — 302-366-5293
DuPont Crop Protection
Stine-Haskell Research Center
P.O. Box 30
Newark, DE 19714-0030

ATTACHMENT J

Data Acquisition for Anticipated Residue and Percent of Crop Treated (OMB 2070-0164)
EPA Questions asked in Consultation

(1) Publicly Available Data

- Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

- If yes, where can you find the data? (Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they don't meet our data needs very well?)

(2) Frequency of Collection

- Can the Agency collect the information less frequently and still produce the same outcome?

(3) Clarity of Instructions

- The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.

- Based on the instructions (regulations, PR Notices, etc.), is it clear what you are required to do and how to submit such data? If not, what suggestions do you have to clarify the instructions?

- Do you understand that you are required to maintain records?

- Considering that there is no required submission format, is it difficult to submit information in ways that are clear, logical and easy to complete?

- Regarding the Voluntary Incident Reporting Forms, do you use them? Are they clear, logical, and easy to complete?

(4) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet.

- What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of "web forms"/XML based submissions via the Agency's Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. Would you be interested in pursuing electronic reporting?
- Are you keeping your records electronically?

- Are you keeping your records electronically? If yes, in what format?

Although the Agency does not offer an electronic reporting option because of CBI-related security concerns at this time,

- would you be more inclined to submit CBI on diskette than on paper?
- what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

(5) Burden and Costs

- Are the labor rates accurate?
- The Agency assumes there are no capital costs associated with this activity. Is that correct?
- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR, e.g., the ICR does not include estimated burden hours and costs for conducting studies, are the estimated burden hours and labor rates accurate? If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.
- Are there other costs that should be accounted for that may have been missed?

Data Acquisition for Anticipated Residue and Percent of Crop Treated

OMB No. 2070- 0164 EPA No. 1911.02

Attachment K

Comments received in to the Consultation Process; EPA Response to Specific Consultation Comments

ATTACHMENT K

Data Acquisition for Anticipated Residue and Percent of Crop Treated (OMB 2070-0164)
Comments received in to the Consultation Process

Respondent #1: *Chris J. Wible*
The Scotts Company
937-644-7012
Chris.Wible@Scotts.com

Date: *July 26, 2004*

(1) Publicly Available Data

(1) Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?
The Scotts Company is a Formulator and does not submit residue data to EPA.

(2) If yes, where can you find the data? (Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they don't meet our data needs very well?)

(2) Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome?
No.

(3) Clarity of Instructions

(1) The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.

(1) Based on the instructions (regulations, PR Notices, etc.), is it clear what you are required to do and how to submit such data?
The Scotts Company does not have any experience with residue data submissions.

(2) If not, what suggestions do you have to clarify the instructions?

(2) Do you understand that you are required to maintain records?
Yes, as registrants, we understand our data retention obligations.

(3) Considering that there is no required submission format, is it difficult to submit information in ways that are clear, logical and easy to complete?
N/A

(4) Regarding the Voluntary Incident Reporting Forms, do you use them? Are they clear, logical, and easy to complete? (
N/A

(4) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet.

(1) What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of "web forms"/XML based submissions via the Agency's Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. Would you be interested in pursuing electronic reporting?
Electronic submissions generally result in faster processing times, both with the registrant and the Agency. Many PMs in RD accept electronic label submission, which we find beneficial. We have not submitted DCI submissions electronically to date but will likely move in that direction in the future.

Are you keeping your records electronically?
If yes, in what format?
Yes, scanned documents, pdf, Word, XML

(2) Although the Agency does not offer an electronic reporting option because of CBI-related security concerns at this time

(1) would you be more inclined to submit CBI on diskette than on paper?
We would be more inclined to submit CBI on paper (CSFs).

(2) what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?
Electronic submission of Toxicology, Product Chemistry, and Master Labels would have a negligible impact on burden reduction. Document preparation is the key driver as opposed to printing/burning/mailing.

(5) Burden and Costs

(1) Are the labor rates accurate?
The labor rates are acceptable industry averages

(2) The Agency assumes there are no capital costs associated with this activity. Is that correct?
This is not correct. If all activities are outsourced, the fees include capital cost of the service provider. If activities are conducted in-house, capital cost are incurred (examples include processing equipment for preparation of Product Chemistry and Acute Tox samples: formulating, analytical, grinding, etc)

(3) Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR, e.g., the ICR does not include estimated burden hours and costs for conducting studies, are the estimated burden hours and labor rates accurate?
The burden hours and total costs appear accurate for Formulators but are likely significant underestimates for the basic AI registrants. The estimate in accurate for registrants utilizing their formulators exemption.

If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.

(4) Are there other costs that should be accounted for that may have been missed?

ATTACHMENT K

Data Acquisition for Anticipated Residue and Percent of Crop Treated (OMB 2070-0164)
EPA Response to Specific Consultation Comments

14) Consultation Comment by J.G. Cummings (DuPont Crop Protection) to Question #5(1) on Burden and Costs:

Labor rates are low if they represent labor costs, benefits, and overhead. The estimates are reasonable if they represent labor cost only.

EPA Response:

The labor cost estimates are meant to cover the burden hours and not overhead costs, such as office IT. However, they are meant to include indirect labor costs, such as benefits. Based on the comment, DuPont's costs may be somewhat higher than the central tendency values used in the draft ICR. The Agency did not modify labor cost estimates based on one company's estimates.

15) Consultation Comment by J.G. Cummings (DuPont Crop Protection) to Question #5(3) on Burden and Costs:

Total number of burden hours are correct, but there should be somewhat more hours of management time and an offsetting reduction in technical time for Type 1 DCIs.

EPA Response:

No specific recommendation for modifying the labor mix was provided and the mix required can vary from company to company, so the Agency did not modify the ICR.